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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,760	07/17/2003	David L. Lewis	Mirus.030.09.2	9319

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EXAMINER

POPA, ILEANA

ART UNIT PAPER NUMBER

1633

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/621,760

Applicant(s)

LEWIS ET AL.

Examiner

Ileana Popa

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' election of polyvinylamine, C6 to C24 alkene, and R1 and R2 are the same in the reply filed on 02/27/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 4 has been cancelled. Claims 1 and 2 have been amended. No new matter was introduced by these amendments to the claims.

Claims 1-3 and 5-9 are pending.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because the application number and the filing date are missing.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the

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reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-3 and 5-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-7, 9, and 13-17 of copending Application No. 10/157,657. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are obvious variants.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The instant claims are drawn to (i) a deliverable composition comprising an amphipatic compound, polyvinylamine and siRNA (claim 1); the amphipatic compound is a 1,4 disubstituted piperazine, wherein the substituting groups are C6 to C24 alkenes (claims 2 and 3), and (ii) a process for delivering a siRNA to an animal cell by using the above-mentioned composition, wherein the animal cell is *in vivo*, *in vitro*, *ex vivo* or the cell is a mammalian cell (claims 5-9).

The application claims are drawn to (i) a deliverable composition

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comprising an amphipatic compound, a polycation and siRNA, wherein the polycation is a polymer (claims 1 and 5); the amphipatic compound is a 1,4 disubstituted piperazine, wherein the substituting groups are C6 to C24 alkenes (claims 6 and 7), and (ii) a process for delivering a siRNA to an animal cell by using the above-mentioned composition, wherein the animal cell is *in vivo*, *in vitro*, *ex vivo* or the cell is a mammalian cell (claims 9 and 13-17). With respect to the limitation of polyvinylamine, the application claims recite the genus of polymeric cation that encompasses the species of polyvinylamine. Thus, the application claims 1, 5-7, 9, and 13-17 anticipate the instant claims 1-3 and 5-9. Since the US Application No. 10/157,657 claims 1, 5-7, 9, and 13-17 embrace all limitation of the instant claims, the instant claims and the application claim are obvious variants of one another.

Claims 1-3 and 5-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 5, and 11 of copending Application No. 10/345,021. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are obvious variants.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The instant claims are drawn to (i) a deliverable composition comprising an amphipatic compound, polyvinylamine and siRNA (claim 1); the amphipatic compound is a 1,4 disubstituted piperazine, wherein the substituting groups are C6 to C24 alkenes (claims

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2 and 3), and (ii) a process for delivering a siRNA to an animal cell by using the above-mentioned composition, wherein the animal cell is *in vivo*, *in vitro*, *ex vivo* or the cell is a mammalian cell (claims 5-9).

The application claims are drawn to a kit containing the composition of the instant claims. Putting the composition in a box containing instruction to use it is not an innovative step over the art. Thus, the application claims claims 1, 2, 4, 5, and 11 anticipate the instant claims 1-3 and 5-9. Since the US Application No. 10/345,021 claims claims 1, 2, 4, 5, and 11 embrace all limitation of the instant claims, the instant claims and the application claim are obvious variants of one another.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3 and 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf et al. (US Patent 5,744,335) in view of Wolfert et al. (Bioconjugate Chem, 1999, 10: 993-1004).

Wolf et al. teach process of delivering a polynucleotide into a cell (i.e., the cell can be *in vivo*, *in vitro*, *ex vivo* or the cell is a mammalian cell), by delivering to the cell a composition comprising an amphipathic compound, a histone, and a selected polynucleic

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acid, wherein the polynucleic acid can be RNA in the form of oligonucleotide (i.e., the RNA can be siRNA) (Summary of the invention, column 7, lines 17-20). The amphipatic compound is a 1,4 disubstituted piperazine, wherein the substituting groups are C6 to C24 alkenes (column 2, lines 40-52). Wolf et al. do not teach polyvinylamine. Wolfert et al. teach that cationic polymers such as polyvinylamine efficiently condensate the nucleic acids and form small complexes with good extracellular stability (Abstract, p. 999, column 1, Results). It would have been obvious to one of skill in the art, at the time the invention was made, to form the deliverable compositions of Wolf et al. by using polyvinylamine to obtain small and stable complexes, as taught by Wolfert et al. The motivation to do so is provided by Wolfert et al. who teach that the use of polyvinylamine results in small complexes that are stable in circulation, can undergo extravasation in the target tissues and can easily enter into the target cells (p. 1003, column 2). One would have been expected to have a reasonable expectation of success because the art teaches that ternary complexes between nucleic acids, amphipatic molecules and polycations can be obtained and successfully used to transfer the desired nucleic acid into cells. Thus, the claimed invention was prima facie obvious at the time the invention was made.

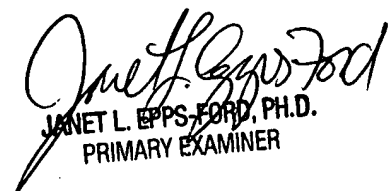
6. No claim is allowed. No claim is free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ileana Popa whose telephone number is 571-272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ileana Popa


JANET L. EPPS-FORD, PH.D.
PRIMARY EXAMINER